510(K) SUMMARY

A. Submitter Information

Manufacturer: Medos International Sárl
Chemin-Blanc 38
2400 Le Locle, Switzerland

Submitter: DePuy Spine, Inc.
325 Paramount Drive
Raynham, MA 02767

SEP 06 2013

Contact Person: Kirsten Lehmuller
325 Paramount Drive
Raynham, MA 02767
Telephone number: 508-828-3291
Fax number: 508-828-3797
Email: klehmull@its.jnj.com

B. Date Prepared July 25, 2013

C. Device Name

Trade/Proprietary Name: SKYLINE® Anterior Cervical Plate System, UNIPLATE® Anterior Cervical Plate System, and UNIPLATE®2 Anterior Cervical Plate System

Common/Usual Name: Spinal System

Classification Name: Spinal intervertebral body fixation orthosis per 21 CFR §888.3060

D. Predicate Device Name

Trade name: SKYLINE® Anterior Cervical Plate System (K052552)
UNIPLATE® Anterior Cervical Plate System (K042544)
UNIPLATE®2 Anterior Cervical Plate System (K082273, K100070)

E. Device Description

The UNIPLATE® and UNIPLATE® 2 Anterior Cervical Plate Systems consist of an assortment of titanium alloy plates and screws. The anterior cervical plates are available in various lengths to accommodate one to three segments of fixation. The screws are available in various sizes and tip geometries.

The SKYLINE® Anterior Cervical Plate System consists of an assortment of titanium alloy plates and screws. The plates have two to six screw hole pairs in various lengths. The screws are available in various sizes and screw-tip geometries. Both constrained and variable screws are available to create a constrained, variable or hybrid configuration.

F. Intended Use

The SKYLINE Anterior Cervical Plate System is indicated for stabilization of the cervical spine from C2 to C7 employing unicortical screw fixation at the anterior face of the vertebral bodies. Specific clinical indications for anterior plating include: instability caused by trauma; instability associated with correction of cervical lordosis and kyphosis deformity; instability associated with pseudoarthrosis as a result of previously failed cervical spine surgery; instability associated with major reconstructive surgery for primary tumors or metastatic malignant tumors of the cervical spine; instability associated with single or multiple level corpectomy in advanced degenerative disc disease, spinal canal stenosis and cervical myelopathy.

The UNIPLATE Anterior Cervical Plate System and UNIPLATE 2 Anterior Cervical Plate System are intended for anterior cervical intervertebral body fixation. These systems are indicated for patients in which stability is desired following anterior cervical fusion for the indications listed below. The intended levels for treatment range from C2 to T1. Indications include symptomatic cervical spondylosis, trauma, fracture, post-traumatic kyphosis or lordosis, tumor, degenerative disc disease (defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies), re-operation for failed fusion, or instability following surgery for the above indications.

The UNIPLATE and UNIPLATE2 Anterior Cervical Plate Systems are also indicated for treatment of spinal stenosis.

F. Summary of Similarities and Differences in Technological Characteristics, Performance and Intended Use

The proposed modifications to the SKYLINE®, UNIPLATE®, and UNIPLATE® 2 Anterior Cervical Plate Systems are identical to the predicate devices (K042544, K052552, K082273, and K100070) except for the proposed devices will be terminally sterilized via gamma radiation. The design, materials, indications, and technology remain identical to the predicate systems.

G. Materials

Manufactured from ASTM F-136 implant grade titanium alloy.

H. Performance Data

Performance data is not provided in this submission.

I. Conclusion

The Substantial Equivalence Justification demonstrates that the devices are as safe, as effective, and perform as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

DePuy Spine, Incorporated
% Ms. Kirsten Lehmuller
Regulatory Affairs Associate
325 Paramount Drive
Raynham, Massachusetts 02767

September 6, 2013

Re: K132324
Trade/Device Name: SKYLINE® Anterior Cervical Plate System, UNIPLATE® Anterior Cervical Plate System, and UNIPLATE®2 Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: August 6, 2013
Received: August 7, 2013

Dear Ms. Lehmuller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K132324

Device Name: SKYLINE® Anterior Cervical Plate System, UNIPLATE® Anterior Cervical Plate System, and UNIPLATE®2 Anterior Cervical Plate System

Indications For Use:

The SKYLINE Anterior Cervical Plate System is indicated for stabilization of the cervical spine from C2 to C7 employing unicortical screw fixation at the anterior face of the vertebral bodies. Specific clinical indications for anterior plating include: instability caused by trauma; instability associated with correction of cervical lordosis and kyphosis deformity; instability associated with pseudoarthrosis as a result of previously failed cervical spine surgery; instability associated with major reconstructive surgery for primary tumors or metastatic malignant tumors of the cervical spine; instability associated with single or multiple level corpectomy in advanced degenerative disc disease, spinal canal stenosis and cervical myelopathy.

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The UNIPLATE and UNIPLATE 2 Anterior Cervical Plate Systems are also indicated for treatment of spinal stenosis.

Prescription Use ___X___ AND/OR Over-The-Counter Use

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(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Caroline Chim -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K132324